Amendments to the Claims

Please cancel Claim 9. Please amend Claims 2, 5, 8, 10, 21, 22, 27, 28 and 89. Please add new Claims 93-96. The Claim Listing below will replace all prior versions of the claims in the application:

Claim Listing

1. (Previously presented) A method of therapeutically treating an uncoupled resorbing bone in a patient, comprising the steps of:
   a) administering an effective amount of a first formulation comprising a bone forming agent into the bone, and
   b) administering an effective amount of a second formulation comprising an anti-resorptive agent into the bone, wherein the anti-resorptive agent is a highly specific cytokine antagonist comprising a monoclonal antibody that inhibits TNF-α.

2. (Currently amended) The method of claim 1 wherein the bone is ~~intact~~ non-fractured.

3. (Previously presented) The method of claim 1 wherein the amount of the first formulation comprising the bone forming agent is effective to increase the density of the bone.

4. (Previously presented) The method of claim 1 wherein the patient is post-menopausal.

5. (Currently amended) The method of claim 1 wherein the uncoupled resorbing bone is a vertebral body.

6-7. (Canceled)

8. (Currently amended) The method of claim 1 wherein the uncoupled resorbing bone is a vertebral body and is adjacent to a fractured vertebral body.

9. (Canceled)

10. (Currently amended) The method of claim 1 wherein the uncoupled resorbing bone is a hip bone.

11. (Withdrawn) A kit for treating an osteoporotic bone, comprising:
    a) a first formulation comprising an osteoconductive material,
    b) a second formulation comprising an effective amount of an anti-resorptive agent, and
    c) a sustained release device adapted to deliver the second formulation into the bone.

12. (Withdrawn) The kit of claim 11 wherein the osteoconductive material comprises calcium and phosphorus.

13. (Withdrawn) The kit of claim 11 wherein the osteoconductive material comprises hydroxyapatite.

14. (Withdrawn) The kit of claim 11 wherein the osteoconductive material comprises collagen.

15. (Withdrawn) The kit of claim 11 wherein the osteoconductive material is in a settable paste form capable of setting up *in vivo* to impart post-treatment mechanical support to the osteoporotic bone.

16. (Withdrawn) The kit of claim 11 wherein the second formulation comprises a highly specific cytokine antagonist.

17. (Withdrawn) The kit of claim 11 wherein the sustained release device comprises a drug pump.

18. (Withdrawn) The kit of claim 11 wherein the sustained release device comprises a bioresorbable material.

19. (Withdrawn) The kit of claim 11 further comprising:

a) an effective amount of a growth factor.

20. (Withdrawn) The kit of claim 11 wherein the sustained release device comprises microspheres.

21. (Currently amended) A method of treating osteoporosis in a patient, comprising administering an effective amount of a formulation comprising an effective amount of a highly specific cytokine antagonist into ~~an~~ at least one uncoupled resorbing bone, wherein the highly specific cytokine antagonist comprises a monoclonal antibody that inhibits TNF-α.

22. (Currently amended) The method of claim 21 wherein ~~the~~ at least one bone is ~~intact~~ into which the formulation is administered is non-fractured.

23. (Previously presented) The method of claim 21 wherein the amount is effective to increase the bone mineral density of the bone.

24. (Previously presented) The method of claim 21 wherein the patient is post-menopausal.

25. (Previously presented) The method of claim 21 wherein the bone is a vertebral body.

26. (Canceled).

27. (Currently amended) The method of claim 21 wherein the ~~highly specific cytokine antagonist inhibits at least one interleukin~~ monoclonal antibody is REMICADE® infliximab.

28. (Currently amended) The method of claim 21 wherein the uncoupled resorbing bone is a vertebral body and is adjacent to a fractured vertebral body.

29. (Original) The method of claim 21 wherein the bone is osteoporotic.

30. (Original) The method of claim 21 wherein the bone is a hip bone.

31. (Withdrawn) An osmotic pump implant for providing sustained delivery of a therapeutic agent into a bone, comprising:

a) a tubular member having a proximal end portion, a distal end portion and a throughbore,

b) a semi-permeable membrane located in the proximal end portion of the tubular member,

c) a piston provided in the tubular member, defining a proximal chamber and a distal chamber,

d) an osmotic engine located in the proximal chamber, and

e) a therapeutic drug located in the distal chamber, wherein the tubular member has an outer surface adapted to anchor to the bone.

32. (Withdrawn) The osmotic pump implant of claim 31 wherein the outer surface has a threadform thereon.

33. (Withdrawn) The osmotic pump implant of claim 31 wherein the outer surface has a hook thereon.

34. (Withdrawn) The osmotic pump implant of claim 31 wherein the outer surface has a porosity effective for inducing bone ingrowth.

35. (Withdrawn) The osmotic pump implant of claim 31 wherein the porosity of the outer surface has an average pore size of between 20 μm and 500 μm.

36. (Withdrawn) The osmotic pump implant of claim 31 wherein the therapeutic drug is a bone forming agent.

37. (Withdrawn) The osmotic pump implant of claim 31 wherein the outer surface is adapted to form a lag screw.

38. (Withdrawn) The osmotic pump implant of claim 31 wherein the therapeutic drug is a growth factor.

39. (Withdrawn) The osmotic pump implant of claim 31 wherein the therapeutic drug is an antibiotic.

40. (Withdrawn) The osmotic pump implant of claim 31 wherein the therapeutic drug is an anti-resorptive agent.

41. (Withdrawn) An osmotic pump implant for providing sustained delivery of two therapeutic agents to a bone, comprising:

a) a tubular member having a proximal end portion, a distal end portion and a throughbore,

b) a semi-permeable membrane located in the proximal end portion of the tubular member,

c) a distal piston provided in the tubular member, defining an intermediate chamber and a distal chamber,

d) a proximal piston provided in the tubular member, defining the intermediate chamber and a proximal chamber,

e) an osmotic engine located in the proximal chamber,

f) a first therapeutic drug located in the distal chamber, and

g) a second therapeutic drug located in the intermediate chamber.

42. (Withdrawn) The osmotic pump implant of claim 41 wherein the tubular member has an outer surface adapted to anchor to the bone.

43. (Withdrawn) The osmotic pump implant of claim 41 wherein the outer surface has a threadform thereon.

44. (Withdrawn) The osmotic pump implant of claim 41 wherein the outer surface has a porosity effective for inducing bone ingrowth.

45. (Withdrawn) The osmotic pump implant of claim 41 wherein the first therapeutic drug is a bone forming agent.

46. (Withdrawn) The osmotic pump implant of claim 45 wherein the bone forming agent is a growth factor.

47. (Withdrawn) The osmotic pump implant of claim 45 wherein the bone forming agent is a BMP.

48. (Withdrawn) The osmotic pump implant of claim 45 wherein the bone forming agent is FGF.

49. (Withdrawn) The osmotic pump implant of claim 45 wherein the second therapeutic drug is an anti-resorptive agent.

50. (Withdrawn) A device for providing sustained delivery of a therapeutic agent into a bone, comprising:

a) a chamber for housing an anti-resorptive agent,

b) an exit port in fluid communication with the chamber,

c) an effective amount of an anti-resorptive agent housed within the chamber, and

d) means for expelling the anti-resorptive agent from the chamber through the exit port.

51. (Withdrawn) A kit for treating an osteoporotic bone, comprising:

a) a first formulation comprising an effective amount of a bone-forming agent,

b) a first sustained release device adapted to deliver the first formulation into the bone,

c) a second formulation comprising an effective amount of an anti-resorptive agent, and

d) a second sustained release device adapted to deliver the second formulation into the bone.

52. (Withdrawn) The kit of claim 51 wherein the bone forming agent is an anabolic agent.

53. (Withdrawn) The kit of claim 51 wherein the bone forming agent is a growth factor.

54. (Withdrawn) The kit of claim 51 wherein the bone forming agent is a BMP.

55. (Withdrawn) The kit of claim 51 wherein the bone forming agent is an antibiotic.

56. (Withdrawn) The kit of claim 51 wherein the second formulation comprises a highly specific cytokine antagonist.

57-58. (Canceled)

59. (Withdrawn) The kit of claim 11 further comprising:

a) an effective amount of a growth factor.

60. (Previously presented) A method of treating an osteoporotic patient having a spinal unit comprising an upper vertebral body, a lower vertebral body, and an intervertebral disc therebetween, comprising: inserting a device into at least one vertebral body adjacent to the intervertebral disc, wherein the device is adapted to deliver an effective amount of a bone forming agent and an anti-resorptive agent into the vertebral body and wherein said anti-resorptive agent comprises a monoclonal antibody that inhibits TNF-α.

61. (Withdrawn) A kit for treating osteoporosis, comprising:

a) an effective amount of a bone forming agent, and

b) an effective amount of a highly specific cytokine antagonist.

62. (Withdrawn) The kit of claim 61 wherein the bone forming agent is an anabolic agent.

63. (Withdrawn) The kit of claim 61 wherein the bone forming agent comprises calcium and phosphorus.

64. (Withdrawn) The kit of claim 61 wherein the bone forming agent comprises an injectable precursor fluid that produces an *in situ* formation of a mineralized collagen composite.

65. (Withdrawn) The kit of claim 61 wherein the bone forming agent comprises collagen.

66. (Withdrawn) The kit of claim 61 wherein the bone forming agent is in a particulate form.

67. (Withdrawn) The kit of claim 61 wherein the bone forming agent is a growth factor.

68. (Withdrawn) The kit of claim 61 wherein the bone forming agent is a BMP.

69. (Withdrawn) The kit of claim 61 wherein the bone forming agent is FGF.

70. (Previously presented) A method of therapeutically treating an uncoupled resorbing bone in a patient, comprising administering an effective amount of a formulation comprising an anti-resorptive agent into the bone, wherein the bone is nontumorous and wherein the anti-resorptive agent is a highly specific cytokine antagonist comprising a monoclonal antibody that inhibits TNF-α.

71. (Withdrawn) A drug delivery implant for providing sustained delivery of a therapeutic agent to a bone, comprising:

a) a drug pump comprising an outer surface and an exit port, and

b) a carrier comprising a recess for receiving the drug pump and means for fastening to the bone.

72. (Withdrawn) The drug delivery implant of claim 71 wherein the drug pump further comprises a flexible tubular member comprising a throughbore, wherein the throughbore is in fluid communication with the exit port.

73. (Withdrawn) The drug delivery implant of claim 72 wherein the drug pump comprises an osmotic engine disposed within a throughbore.

74. (Withdrawn) The drug delivery implant of claim 71 wherein the drug pump contains a first formulation comprising an effective amount of a bone-forming agent.

75. (Withdrawn) The drug delivery implant of claim 71 wherein the drug pump contains a first formulation comprising an effective amount of an anti-resorptive agent.

76. (Withdrawn) The drug delivery implant of claim 71 wherein the carrier comprises a radio-opaque material.

77. (Withdrawn) The drug delivery implant of claim 71 wherein the carrier is made of a material having a modulus of elasticity of between about 0.1 and about 10 GPa.

78. (Withdrawn) The drug delivery implant of claim 71 wherein the carrier has an outer surface having a threadform thereon.

79. (Withdrawn) The drug delivery implant of claim 71 wherein the drug pump has a cylindrical outer surface, the carrier comprises a throughbore and the cylindrical outer surface is adapted to fit within the throughbore.

80. (Withdrawn) A kit for treating osteoporosis, comprising:

a) a bone anchor comprising:

i) an outer surface having at least one exit hole,

ii) a distal end portion having at least one entry hole, and

iii) a throughbore in fluid communication with the entry and exit holes;

b) a first formulation comprising an effective amount of a bone forming agent, and

c) a second formulation comprising an effective amount of an anti-resorptive agent.

81. (Withdrawn) The kit of claim 80 wherein the bone forming agent is an anabolic agent.

82. (Withdrawn) The kit of claim 80 wherein the bone forming agent comprises calcium and phosphorus.

83. (Withdrawn) The kit of claim 80 wherein the bone forming agent comprises hydroxyapatite.

84. (Withdrawn) The kit of claim 80 wherein the bone forming agent comprises collagen.

85. (Withdrawn) The kit of claim 80 wherein the bone forming agent is in a particulate form.

86. (Withdrawn) The kit of claim 80 wherein the bone forming agent is a growth factor.

87. (Withdrawn) The kit of claim 80 wherein the bone forming agent is a BMP.

88. (Withdrawn) The kit of claim 80 wherein the bone forming agent is FGF.

89. (Currently amended) A method of therapeutically treating an uncoupled resorbing bone in a patient, comprising the steps of:

a) administering an effective amount of a first formulation comprising a bone forming agent into the bone, and

b) administering an effective amount of a second formulation comprising an anti-resorptive agent into the bone, wherein the anti-resorptive agent is a highly specific cytokine antagonist comprising a monoclonal antibody that inhibits TNF-

α, wherein the second formulation ~~is~~ remains in the bone in an effective amount for at least one month.

90. (Withdrawn) The method of Claim 1, wherein the bone forming agent is released from a sustained release device.

91. (Previously presented) The method of Claim 60, wherein the anti-resorptive agent comprises REMICADE® infliximab.

92. (Previously presented) The method of Claim 1, wherein the anti-resorptive agent comprises REMICADE® infliximab.

93. (New) The method of Claim 1, wherein the uncoupled resorbing bone is osteoporotic or osteopenic.

94. (New) The method of Claim 21 wherein the formulation remains in the bone in an effective amount for at least one month.

95. (New) The method of Claim 60 wherein the device is adapted to deliver the bone forming agent and the anti-resorptive agent into the vertebral body for at least one month.

96. (New) The method of Claim 70 wherein the formulation remains in the bone in an effective amount for at least one month.